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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,322	10/31/2001	James R. Komorowski	AMBHNC.008A	3387

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
PATTEN, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1651	5

DATE MAILED: 09/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,322	KOMOROWSKI ET AL.	
	Examiner	Art Unit	
	Patricia A Patten	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *10-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a composition comprising alpha-lipoic acid and a chromium complex, classified in class 514, subclass 558 for example.

II. Claims 10-13, drawn to a composition comprising a chromium complex, an alpha-lipoic acid, a cyclooxygenase inhibitor, a mucolytic and a salicin-containing herb, classified in class 424, subclass 725 for example.

III. Claims 14-24, drawn to a method for improving insulin sensitivity in a subject in need thereof comprising administration of a composition comprising alpha-lipoic acid and a chromium complex, classified in class 514, subclass 2 for example

The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

case, the combination as claimed does not require the particulars of the subcombination as claimed because the chromium complex of the combination (Group II) could be an entirely different chromium complex than the complex as claimed in the subcombination. For example, the chromium complex of the combination may be a chromium-protein complex and would therefore provide for a different pharmaceutical effect than administration of a chromium complex which only comprises chromium picolinate for example. The subcombination has separate utility such as a treatment for alcoholism.

Inventions (I and III) and (II and III) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the Group III is drawn to a method for improving insulin intolerance with a composition comprising specific chromium complexes, wherein additional ingredients are added into the composition such as a cyclooxyganase inhibitor, a mucolytic and a salicin-containing herb. As noted *supra*, Group I is specific to the types of chromium complexes, but does not include constituents in the composition such as a mucolytic and a salicin-containing herb. Thus, the method of Group III is patentably distinct from the composition of Group I because the method employs a different composition which would consequently provide for a different pharmaceutical effect. Further, because Group II does not particularly point out what 'chromium complex' is used, as discussed *supra*, the chromium complex may be a protein-chromium

complex than recited in Group III which would provide for a different pharmaceutical effect when administered to an individual.

The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Because these inventions are distinct for the reasons given above and the search required for each Group is not required for the others, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ned Israelsen on 9/13/02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 10-26 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-9 have been presented for examination on the merits.

It is noted that Claims 1 and 8 recite 'consisting essentially of'. Applicant has not defined the metes and bounds of this phrase, and thus, the Examiner cannot ascertain what can, or cannot be included in the composition especially in light of the Specification which incorporates several different embodiments with regard to the compositions which include the chromium-complex.

Thus, the Examiner has treated 'consisting essentially of' as if it read 'comprising' and examined the claims on the merits accordingly.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2 and 7-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Carthron (US 6,277,842). Claims 1-2 and 7-8 are drawn to a composition comprising a chromium complex and alpha-lipocic acid. Claims are further narrowed to specific chromium complexes such as chromium picolinate, wherein the chromium complex and alpha-lipoic acid are in a ratio of between about 1:25 to 1:1000 and wherein the composition additionally contains a chelating agent.

Carthron (US 6,277,842) disclosed an oral composition which included chromium picolinate and alpha-lipoic acid as well as other constituents such as creatine, thiamine and niacin (claims 1-10) for promoting weight loss. Carthron disclosed that the niacin was present in the form of either nicotinic acid or nicotinamide (col.3, lines 64-65) which are both chelating agents. The method recites a composition which contains the chromium picolinate and alpha-lipoic acid in the Instantly claimed ranges; i.e., 30 mcg chromium picolinate: 30-2500 mcg alpha-lipoic acid = 1/8 - 1/1000 (col.5, lines 42-47), thus anticipating claim 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior

art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carthron (US 6,277,842). The nature of claims 1-2 and 7-8 were discussed *supra*. Claims 3-4 are drawn to wherein the composition is incorporated into a pharmaceutically effective carrier such as tablets, and emulsions for example. Claims 6 and 9 are drawn to wherein the tablet, capsule or microbead is coated with an enteric coating, and wherein the chelating agent is picolinic acid, nicotinic acid or both.

The teachings of Carthron ('842) were discussed *supra*. Carthron did not specifically teach the composition with an enteric coating, wherein the chelating agent was specifically nicotinic acid or picolinic acid or both or wherein a carrier was added to the pharmaceutical composition.

Although Carthron did not specifically teach wherein the composition was enterically coated, Carthron did specifically suggest the use of coated tablets "...to delay disintegration and absorption in the gastrointestinal tract and thereby provide a sustained action over a longer period of time" (col.5, lines 42-45). Thus, one of ordinary skill in the art would have been motivated to have enterically coat the composition in order to achieve the delay of disintegration in the gastrointestinal tract as suggested by Carthron.

Although Carthron did not specifically teach wherein the chelating agent was specifically nicotinic acid or picolinic acid or both, Carthron did suggest the incorporation of nicotinic acid

into the composition which is a chelating agent. Thus, one of ordinary skill in the art would have been motivated to have incorporated nicotinic acid into the mixture as the preferred form of niacin because nicotinic acid would have "..promoted continued activation of the citric acid cycle..." as disclosed by Carthron (col.4, lines 30).

Although Carthron did not explicitly display wherein the composition was admixed with a carrier and incorporated into a tablet and/or capsule for example, Carthron did *specifically suggest* wherein the oral compositions were in a forms such as tablets, suspensions, powders, granules, emulsions, capsules, syrups or elixirs (col.5, lines 19-28). Carthron taught that the components could have been provided in various forms, and further added that 'Compositions intended for oral use may be prepared according to any method known in the art for the manufacture of pharmaceutically acceptable compositions' (col.5, lines 22-24). Thus, although Carthron did not *explicitly* disclose a list of ingredients along with carriers, i.e, in the form of a table or include carriers in the claims Carthron clearly suggested the use of carriers (col.5, lines 29-41).

One of ordinary skill in the art would have been motivated to have added the active ingredients into a formulation such as a tablet along with pharmaceutically acceptable carriers as suggested by Carthron, in order to have created a supplement for ease of administration/delivery.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carthron (US 6,277,842) in view of de la Harpe et al. (US 5,980,905). The nature of claims 1-4 and 6-9 were

discussed *supra*. Claim 5 is drawn to wherein the carrier is a microbead and wherein the chromium complex and alpha-lipoic acid are coated on said microbead.

The teachings of Carthron ('842) were discussed *supra*. Carthron did not specifically teach wherein the composition was the chromium complex and α-lipoic acid were coated on a microbead.

de la Harpe et al. (US 5,980,905) disclosed a composition for lowering blood glucose level and increasing lean body mass which comprised, as active ingredients, chromium complexes and chelating agents such as picolinic acid or nicotinic acid (claim 1 for example). De la Harpe et al. taught that this formulation was advantageously coated onto microbeads made of sugar or microcrystalline cellulose and optionally enterically coated (col.6, line 66- col.7 line 30). Thus, the incorporation of compositions which contained chromium were known to have been delivered via coating on microbeads made of sugar.

To reiterate, Carthron disclosed that 'Compositions intended for oral use may be prepared according to any method known in the art for the manufacture of pharmaceutically acceptable compositions.' One of ordinary skill in the art would have been motivated to have coated the composition, as disclosed by Carthron, onto a beadlet as disclosed by de la Harpe et al. because this would have been an acceptable form of delivery for the composition, satisfying the

requirement of 'any method known in the art fro the manufacture of pharmaceutically acceptable compositions.' Further, one would have recognized that the compositions disclosed by both Carthron and de la Harpe et al. were similar, and would have been beneficially administered in similar ways.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon P. Weber, Ph.D.
Primary Examiner